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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,090 | 11/15/2001 | Gordhanbhai Patel | 3800.001 | 6317 |
| 30589 | 7590 | 06/01/2006 | EXAMINER | |
| DUNLAP, CODDING & ROGERS P.C. PO BOX 16370 OKLAHOMA CITY, OK 73113 | | | CROSS, LATOYA I | |
| | | | ART UNIT | PAPER NUMBER |

1743

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/009,090 | PATEL, GORDHANBHAI | |
| | Examiner | Art Unit | |
| | LaToya C. Younger | 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2006 has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 62 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,287,518 to Ignacio et al.

Ignacio et al teach a composition and device for monitoring sterilization processes.

The composition comprises a dye (indicator) and a halogen source (activator) within a binder resin (polymer), as recited in claim 50 (col. 3, lines 8-9). Phenol red, a pH indicator, is disclosed as an example of the color changing dye,(col. 3, lines 10-19). After exposure to sterilization, the composition turned from red to yellow (col. 10, line 66 – col. 11, line 15). With respect to the activator, Ignacio et al teach

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halogen sources including as alkali metal halides such as potassium bromide (col. 3, lines 31-39). The reference also discloses using quaternary amines, such as tetra alkyl ammonium bromides (col. 6, lines 57-60). Figure 1 of the reference shows a multi-layered device wherein the top layer (30) is made of polymeric material (col. 10, lines 4-6) wherein the sterilant is exposed to this top layer. Ignacio et al teach dissolving the components of the composition in an alcohol solvent and applying the composition to blotter paper (col. 4, lines 38-62). The reference further teaches that the composition may be in the form of ink and the substrate may be in the form of a strip or label (col. 3, line 64 – col. 4, line 19, col. 7, line 21). Ignacio et al teach that the device may be used to monitor peracetic acid or hydrogen peroxide sterilization processes (col. 5, lines 49-59). Specifically, Ignacio et al teach that the indicator device is made and then attached to a bottle that is exposed to hydrogen peroxide sterilization (col. 4, lines 55-62). Within 10 minutes, a color change from yellow to red is observed. The Ignacio et al reference further disclose that the sterilization indicators may be used to monitor sterilization processes that include a plasma step (col. 5, lines 49-59).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (US 6,287,518) in view of US patent 6,020,405 to Matzinger et al.

Ignacio et al disclose a composition and device for monitoring sterilization processes.

The composition comprises a dye (indicator) and a halogen source (activator) within a binder resin (polymer), as recited in claim 50 (col. 3, lines 8-9). Phenol red, a pH indicator, is disclosed as an example of the color changing dye, (col. 3, lines 10-19). After exposure to sterilization, the composition turned from red to yellow (col. 10, line 66 – col. 11, line 15). With respect to the activator, Ignacio discloses halogen sources including as alkali metal halides such as potassium bromide (col. 3, lines 31-39). The reference also discloses using quaternary amines, such as tetra alkyl ammonium bromides (col. 6, lines 57-60). Figure 1 of the reference shows a multi-layered device wherein the top layer (30) is made of polymeric material (col. 10, lines 4-6) wherein the sterilant is exposed to this top layer. Ignacio discloses dissolving the components of the composition in an alcohol solvent and applying the composition to blotter paper (col. 4, lines 38-62). The strip is attached to a bottle exposed to hydrogen peroxide sterilant (col. 4, lines 57-59). The reference further teaches that the composition may be in the form of ink and the substrate may be in the form of a strip or label (col. 3, line 64 – col. 4, line 19, col. 7, line 21). With respect to claims 62-63, where Applicants claim the use of the device in monitoring sterilization processes, Ignacio et al disclose that the device may be used to monitor peracetic acid or hydrogen peroxide sterilization processes (col. 5, lines 49-59). Ignacio et al further disclose that the sterilization indicators may be used to monitor sterilization processes that include a plasma step.

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Ignacio et al differ from the instant invention in that there is no disclosure of the a zinc compound or polyaziridine in the ink sterilization monitoring composition.

Matzinger et al is directed to ink compositions containing crosslinked cellulosic polymers (such as those disclosed in Ignacio et al) and a pigment or dye. The crosslinking takes place by associating the polymers with a crosslinking agent such a zinc compound – zinc palmitate or zinc stearate (col. 5, lines 29-35). Matzinger et al teach that cellulosic polymers that are crosslinked with organo-metallic compounds provide ink formulations that are good or better in color, adhesion and tack, as well as significant improvements in dye dispersions and stability (col. 13, lines 64-67). It would have been obvious to one of ordinary skill in the art to use a crosslinked cellulosic binder resin as the polymer in Ignacio et al to provide ink compositions that have superior dye dispersion and stability.

6. Claims 51, 52, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujisawa (US patent 5,087,659) in view of Omatsu et al (US patent 6,117,685).

Fujisawa discloses ink compositions for steam sterilization comprising an ink formulation, an indicator and an activator. The ink formulation comprises phenolic resin dissolved in a suitable solvent (col. 1, line 68 – col. 2, line 4. The indicator is a cyanine dye, also dissolved in a solvent, which is color-changeable in response to sterilization. The ink compositions further contain alkali metal salts, which may be used as activating agents (col. 4, lines 13-23). At col. 5, lines 4-11, Fujisawa discloses applying the ink compositions to a suitable substrate (paper, glass, etc) as recited in claims 60, 61.

Fujisawa differs from the instant invention in that there is no teaching of an ink extender in the ink formulations.

Omatsu et al teach ink formulations for sterilization detection. The reference teaches that ink extenders are commonly used in inks as supplemental formulating agents (col. 6, lines 41-44). Omatsu et

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al further teach that the addition of extenders allows detection sensitivity of the sensors to be controlled. It would have been obvious to one of ordinary skill in the art to incorporate an ink extender into the ink compositions of Fujisawa to enhance the detection of the sterilization.

It is noted that Fugisawa does not teach that the devices are for monitoring plasma sterilization. However, this is considered to be Applicants' intended use, which is insufficient to patentably distinguish the instant claims over Fugisawa. See MPEP 2111.02.

7. Claims 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fujisawa and Omatsu et al as applied to claims 51, 52, 60 and 61 above, and further in view of US patent 6,096,533 to Tautvydas.

The disclosures of Fujisawa and Omatsu et al are described above. Neither reference teaches an indicator selected from phenol red, cresol purple or pararosaniline as recited in claim 53.

Steam sterilizations indicators such as phenol red, cresol purple or pararosaniline are known in the art and are taught by Tautvydas. Tautvydas teaches steam sterilization indicator compositions. As the indicator, the reference teaches phenol red, cresol purple, as well as other indicators (col. 7, lines 1-20). The reference further states that indicators are suitable for color-changing in response to pH changes during sterilization. It would have been obvious to one of ordinary skill in the art to substitute the pH indicators of Fugisawa for those taught by Tautvydas, since those are known to be suitable indicators of sterilization processes.

8. Claims 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fugisawa and Omatsu et al as applied to claims 51, 52, 60, 61 above, and further in view of US patent 6,020,405 to Matzinger et al.

The disclosures of Fujisawa and Omatsu et al are described above. Neither reference teaches the

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supplemental ink additives recited in claims 54-59.

Matzinger et al is directed to ink compositions containing crosslinked polymers and a pigment or dye. The ink compositions may be used in gravure or flexographic printing processes and may be in the form of an emulsion (col. 3, lines 16-18, col. 4, lines 62-65; col. 7, lines 51-56). The polymers in the ink composition may be styrene-acrylic polymers (col. 4, lines 59-60). The crosslinking takes place by associating the polymers with a crosslinking agent such a zinc compound – zinc palmitate or zinc stearate (col. 5, lines 29-35). Matzinger et al further teach conventional additives in ink compositions such as plasticizers (col. 5, lines 16-20). It would have been obvious to one of ordinary skill in the art to incorporate conventional additives (cross-linking agents and plasticizers) into ink compositions of Fujisawa et al comprising styrene-acrylic polymers and pigments/dyes to provide ink formulations suitable for gravure or flexographic printing processes that have improved ink properties, i.e. good color, adhesion and tack, as well as improved pigment dispersion and stability.

Relevant Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent 6,117,492 teaches using polyaziridine compounds as crosslinking agents in coatings made with styrene-acrylate polymers.

Response to Arguments

10. Applicant's arguments with respect to new claims 50-63 have been considered but are moot in view of the new ground(s) of rejection.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 10:30 a.m. - 8:00 p.m. and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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